

Remarks

Rejection under 35 U.S.C. § 112, first paragraph and second paragraph

The rejection of claim 95 under 35 U.S.C. § 112, first paragraph and second paragraph has been obviated by the amendment to the claims. As such, applicant requests the withdrawal of same.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 121 and 122 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakatsuka et al. (U.S. Patent No. 4,076,846; hereinafter, Nakatsuka). Applicant traverses said rejection

Applicant has amended claim 121 to recite:

“A particle comprising alginate and a starch-emulsifier complex, wherein the starch-emulsifier complex is partially or completely insoluble in water.”

It is well established, as a matter of law, that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

Nakatsuka described a water-soluble, edible thermoplastic molding composition that includes a starch material, an inorganic salt of a protein, an organic plasticizer and an edible lubricant. A water-soluble material such as Nakatsuka's is mutually exclusive of applicant's particle that includes a partially or completely insoluble complex and as such, Nakatsuka cannot anticipate applicant's claim 121.

Accordingly, applicant respectfully submits that claim 121 is patentably distinguishable over Nakatsuka. Withdrawal of this rejection under 35 U.S.C. §102(b) is requested.

Claim Rejections under 35 U.S.C. § 103(a)

1. Claims 87-96, 98, 103, 104, 108-112, 114, 121 and 122 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kürzinger (U.S. Patent No. 6,303,175; hereinafter, Kürzinger) in view of Nakatsuka

and Tester (WO 99/53902). Applicant traverses said rejection and submits that the proposed combination does not in any way establish a *prima facie* case of obviousness.

Claim 87 has been amended to recite:

“An animal feed composition comprising a particle ranging in size from the about 100 μ m to about 1 cm, wherein such particle comprises alginate and a starch-emulsifier complex, wherein the alginate comprises from about 0.5 to about 2.0 percent by wet weight of the particle, the emulsifier comprises a ratio to the starch from about 1:10 to about 10:1, and the starch-emulsifier complex is partially or completely insoluble in water.”

Applicant's particles include a starch-emulsifier formed complex, which is stabilized by the interaction between the starch and the emulsifier. Importantly, the increased hydrophobicity of the emulsifier helps to prevent, or to delay, penetration of water or gastric juices into the matrix once formed into microparticles.

The starch-emulsifier complex of the present invention is created by placing starch in a sodium hydroxide solution at a temperature range of 20 to 65° C until the starch granules are fully absorbed with water and reach equilibrium. The use of a sodium hydroxide solution necessarily means that the gelatinization of the starch occurs at an alkaline pH. An emulsifier is then added to prevent the reannealing of the starch grains upon cooling and neutralization; thus, the creation of a starch-emulsifier complex. The alginate is then added to the starch-emulsion complex but this alginate must not dissolve the starch-emulsifier complex, as expressly stated in applicant's specification and recreated below:

[0057] The alkalinity of the product is slowly reduced to a pH of approximately 7.5-8 by the addition of acid. The starch and emulsifier complex can also be co-processed with hydrocolloids, gums, polymers, modified starches, and/or combinations thereof to change the water binding capacity of the starch-emulsifier compositions. For example, xanthan gum, alginate, carrageenan, carboxymethyl cellulose, methyl cellulose, guar gum, gum arabic, locust bean gum, and/or combinations thereof can be added to the starch-emulsifier compositions at any time after neutralization, as long as the additional ingredient(s) does not dissolve the formation of the amylose-emulsifier complex. Finally, the slurry composition is allowed to cool to room temperature.

The bioactive agent is then added and pellets are formed to provide particles ranging from about 100um to 1 cm.

The Office contends that the Kurzinger describes all the components of applicant's claimed invention. Applicant vigorously disagrees. Kurzinger describes a gel-like fish food that can be used to replace frozen food which in warmer waters degrades too quickly. Kurzinger provides for a feed with high viscosity that stays in the molded form in cool water so that fish have the ability to eat the food having the consistency of a frozen feed. The process of preparation includes the combination of the animal feed with the gel forming agents to form a highly viscous mixture that retains its form and **does not dissolve** in cold water.

Specifically, Kurzinger for a multiplicity of gel formers and somehow from the list below the Office has homed in on just starch, lecithin and alginate. Applicant questions how this is possible without using Applicant's specification as a blueprint for a hunting expedition.

Notably, there are hundreds of different gel former in the list below and no guidance that one is more important than another except that agar agar is preferred by Kurzinger

Suitable gel formers can be synthetic, semisynthetic or of natural origin.

- 0 Synthetic gel formers are, for example, cellulose ethers, such as alkyl- and/or hydroxyalkyl-substituted cellulose ethers with 1 to 4 carbon atoms in the alkyl chain, preferably methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxyethylmethyl-cellulose,
- 5 hydroxyethylethylcellulose, hydroxypropyl-methylcellulose or the like. HPMC is especially preferred.

Natural gel formers or semi-synthetic gel formers or ones obtained in biotechnological ways are hydrocolloids of vegetable, animal or bacterial origin, such as e.g.

- 0 polysaccharides, vegetable gums or collagens. These are obtained from natural algae, natural vegetable seed gums, natural vegetable juices, natural fruit extracts, biosynthetic gums, biosynthetically modified starches or cellulose materials or exocellular polysaccharides. There are suitable, for
- 5 example, pectins, alginates, carrageenan, agar agar, guar gum, gum arabic, tragacanth, Karaya gum, ghatti gum, locust bean flour, arabian, gellan, konjacmannan, galactomannan, funoran, sago, tara gum, xanthans, acetan, welan, rhamsan, furcelleran, succinoglycan, scleroglycan,
- 0 schizophyllan, tamarind gum, curdlan, pullulan, dextran or gelatine. Especially preferred is agar agar.

The mentioned gel formers can be used alone or preferably in synergistic combinations improving the acceptance and the properties of the feed.

- 5 For the improvement of the properties and, above all, of the acceptance, the feed mixtures according to the invention can additionally contain softeners or moisture retainers, such as e.g. glycerol, polyethylene glycol, propylene glycol, glycine, sorbitol, mannitol, canesugar, maize syrup,
- 0 fructose, dioctyl sodium sulphosuccinate, triethyl citrate, tributyl citrate, 1,2-propylene glycol, mono-, di- or triacetates of glycerol, acetamide, formamide or lactamide, namely, alone or in synergistic combinations.

For the improvement of the consistency and of the

- 5 holding together of the feed mixture, additional chelate formers can be contained therein, such as e.g. ethylenediamine-tetraacetic acid, acetic acid, boric acid, citric acid, gluconic acid, lactic acid, phosphoric acid, tartaric acid, as well as salts of the said acids or
- 0 metaphosphates, dihydroxyethylglycine, lecithin or beta-cyclodextrin or mixtures thereof.

Clearly reviewing this reference it is very evident that a starch/emulsifier complex is not formed as a separate entity, but instead, everything is thrown into the same pot. As such, this reference could not possibly form the starch-emulsifier complex of the present invention because

the method of preparing such a complex was not known at the time of filing of the Kurzinger reference. Thus, this reference could not possible form a starch-emulsifier complex as in the present invention.

The Office has added the Nakatsuka reference to fix the problems of Kurzinger, but of course, this reference really does not help. Nakatsuka provides for a water soluble and moldable composition as shown below from column 3:

According to this invention, there is provided a water-soluble and edible thermoplastic molding composition comprising a starch material, an inorganic alkali salt of a protein material, an edible low-molecular-weight organic plasticizer, and an edible lubricant.

The inorganic alkali salt of a protein material is important, because Nakatsuka expressly states that the starch and inorganic alkali salt of a protein material form a chemical reaction that forms some type of union as described in column 6, and recreated below:

The mixture of a starch material and a neutral inorganic alkali salt of a protein material according to this invention is not a simple mixture in which both materials in amorphous form are uniformly dispersed, but it seems that some degree of union has been established between both materials by chemical reaction, thus contributing to the improvement in physical properties.

Chemical reaction

The inorganic salts of proteins is described in Nakatsuka at column 4 and recreated below:

The "inorganic alkali salt" of protein materials as
 15 herein referred to means a salt of protein material with an alkali metal or an alkaline earth metal. The protein materials suitable for use in forming such a salt are those derived from various animals, plants, and microorganisms by concentration or extraction, such as casein (derived from milk, soybean, etc.), albumin (derived from
 20 blood or egg), collagen, gelatin, glue, gluten, etc. These are used each alone or in mixtures.

Notably, by reviewing the Nakatsuka disclosure it is very evident that the starch-emulsifier complex of the present invention could not be formed by the preparation of the Nakatsuka compositions. Specifically, Nakatsuka combines the starch and inorganic alkali salt of a protein to form a mixture and then adds an edible hydrophilic plasticizer that is capable of swelling the binary blend of the inorganic salt of a protein and the starch. Finally a lubricant is added to the blend to increase moldability and easy release from the mold. There is no disclosure, teaching or suggestion that a starch-emulsifier complex is or could be formed in the Nakatsuka's blends.

Further, even if one adds the disclosure of Nakatsuka to Kurzinger, there is no disclosure or guidance for the particles of the presently claimed invention wherein there is a specific entity that is the starch/emulsion complex.

The Office has implied that one skilled in the art considering Kürzinger and Nakatsuka would knowingly select alginate from a laundry list of gel formers and plasticizers from Kürzinger and Nakatsuka, respectively. It is unclear why one skilled in the art considering Kürzinger and Nakatsuka would knowingly select alginate from each list, especially when the favored gel former in Kürzinger is agar agar and the favored plasticizer in Nakatsuka is water or glycerol. The Office recognized this shortcoming and went back to look for additional prior art, in the attempt to fill in the huge gaps of the Nakatsuka and Kurzinger combination. Applicant insists that the addition of Tester does not overcome the shortcomings of the Kurzinger/Nakatsuka combination.

According to the Office, Tester teaches that the combination of alginate and starch are symbiotic and thus a skilled artisan would have motivation to specifically select the combination from Kurzinger and Nakatsuka. Of course the Office is once again missing the point, that being, that applicant's invention includes firstly a starch/emulsifier complex that is then mixed with the alginate. It is important that the alginate DOES NOT dissolve the formation of the starch/emulsifier complex as again shown below:

[0057] The alkalinity of the product is slowly reduced to a pH of approximately 7.5-8 by the addition of acid. The starch and emulsifier complex can also be co-processed with hydrocolloids, gums, polymers, modified starches, and/or combinations thereof to change the water binding capacity of the starch-emulsifier compositions. For example, xanthan gum, alginate, carrageenan, carboxymethyl cellulose, methyl cellulose, guar gum, gum arabic, locust bean gum, and/or combinations thereof can be added to the starch-emulsifier compositions at any time after neutralization, as long as the additional ingredient(s) does not dissolve the formation of the amylose-emulsifier complex. Finally, the slurry composition is allowed to cool to room temperature.

Why would a skilled artisan use any of the information from the three references and be directed to forming a starch/emulsifier complex and then adding the same with an alginate. Clearly there is no guidance and the Office is not allowed to speculate on such a combination.

The Office's attention is directed to the Federal Circuit's decision in *Environmental Designs v. Union Oil Co. of Cal.*, 218 USPQ 865 (Fed. Cir. 1983), where the court stated:

"All the pieces of the present invention were known in the art, i.e., the equations for hydrogenation and hydrolysis of sulfur compounds, the simultaneity of chemical reaction, and the components of the Claus effluent. That all elements of an invention may have been old (the normal situation), or some old or some new, or all new, is however, simply irrelevant. Virtually all inventions are combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art."

Thus, the fact that isolated elements of an invention are "disclosed" in the prior art is alone insufficient. The test is not whether isolated "elements" are known, but rather whether the subject matter of the invention "as a whole," in light of all the teachings of all the cited references in all of their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made.

Applicant reminds the Office that under Graham, and as required by MPEP §§ 2111 and 2141.02, the Office must ascertain the differences between the claimed invention and the prior art, and must consider both the invention and the prior art as a whole. Thus, even in light of the KSR decision, the Office must consider the inventions of any cited references in their respective entireties. Certain individual features from the references may not be arbitrarily chosen (while equally arbitrarily discarding other

disclosed features) to merely lump together disparate features of different references as a mosaic in an attempt to meet the features of the rejected claims. Thus, the Office is not allowed to pick and choose just certain parts of different references and combine them, but instead, the references in their entirety must be considered.

Further, the MPEP § 2143.01 V – VI states that:

“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. ... [and] If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”

As previously stated, Applicant submits that Kürzinger intended the feed form to be insoluble while Nakatsuka teaches a water-soluble product. Based on the Office’s proposed combination, applicant questions, should the final product be insoluble per Kürzinger or water-soluble per Nakatsuka? This is an important question when you consider the reasonableness of combining two pieces of prior art and what the expectation of success will be. Assuming the final product of the Examiner’s proposed combination were insoluble, Nakatsuka would be rendered unsatisfactory for its intended purpose and vice versa. As such, a *prima facie* case of obviousness cannot exist. See *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicant reminds the Office that the ruling in *In re Ratti*, (270 F.2d 810 (CCPA 1959)) states that where a proposed modification would change the principle of operation of the prior art invention being modified, then the teachings are not sufficient to establish a *prima facie* case of obviousness. According to the Board in *Ex Parte Vito Cellini*, (Appeal 2008-4104, BPAI 2008), “a change in the basic principles” refers to change that is fundamental in scope so as to relates to scientific or technical principles of operation.

Thus, the suggested combination of references would require a substantial change in the elements of the prior art as well as a change in the basic scientific principals under which the prior art was designed to operate. As such, the proposed combination does not establish a *prima facie* case of obviousness because the combination of references fundamentally change the “basic principals” under which the prior art was designed to operate. Clearly there is no guidance for picking and choosing from either reference to go in the direction of applicant’s claimed invention unless of course the Office is again using the applicant’s

specification as a blueprint for a hunting expedition, which we all know is considered to be impermissible hindsight.

In light of the foregoing discussion and the fact that all of claimed limitations are not disclosed or suggested by the cited combination and/or the proposed combination will render the invention of Kürzinger and Nakatsuka either inoperable or no longer functioning as intended, it is clear that the Office has not met its burden of establishing a *prima facie* case of obviousness.

2. Claims 87, 97-100, 103, 105-107, 113, 115 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kürzinger in view of Nakatsuka as applied to claims 87-96, 98, 103, 104, 108-112, and 114 above, and further in view of Villamar et al. (WO 02/00035; hereinafter, Villamar). Applicant traverses said rejection.

Villamar is directed to a bioactive food complex product, method for preparing a bioactive food complex product, and method for controlling disease. Notably, Villamar does not teach or suggest the inclusion of starch in the Villamar food complex and as such, Villamar completely fails to teach the starch-emulsifier complex claimed herein. Accordingly, Villamar does not cure the deficiencies of Kürzinger and Nakatsuka.

Thus, the Office has failed to present a *prima facie* case of obviousness for applicant's claims in view of Kürzinger, Nakatsuka, and Villamar. As such, applicant respectfully requests that the rejection under 35 U.S.C. 103(a) in view of Kürzinger, Nakatsuka, and Villamar be withdrawn.

Rejoinder of Method Claims

Applicant requests that when the product claims of the present invention are found patentable, all pending method of making and using claims are examined through the rejoinder procedure in accordance with MPEP §821.04. Rejoinder is proper when an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product for examination through rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

Petition for Extension and Fees Payable

Applicant petitions for a one month extension to extend the response due date of May 3, 2010 to June 3, 2010 and the fee of \$65.00 is being paid herewith by electronic transfer. If any additional fee is found due for entry of this amendment, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Orwig, reconsider the patentability of all pending claims, in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Orwig is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,

/mariannefuierer/

Marianne Fuierer
Attorney for Applicants
Moore & Van Allen, PLLC
Telephone: (919) 286-8089
Facsimile: (919) 286-8199